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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 40206.1USC1 2591 09/829,678 04/09/2001 William W. Cimino 7590 06/17/2003 23552 MERCHANT & GOULD PC **EXAMINER** P.O. BOX 2903 THISSELL, JEREMY MINNEAPOLIS, MN 55402-0903 ART UNIT PAPER NUMBER 3763 DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	-	a
	Application No.	Applicant(s)
	09/829,678	CIMINO, WILLIAM W.
Office Action Summary	Examiner	Art Unit
	Jeremy T. Thissell	3763
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1) Responsive to communication(s) filed on <u>02 J</u>	<u>lune 2003</u> .	
2a)⊠ This action is FINAL. 2b)□ Th	is action is non-final.	
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4) Claim(s) 12-17 is/are pending in the application	n.	
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>12-17</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents	s have been received.	
2. Certified copies of the priority documents	s have been received in Applicati	ion No
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)
S. Patent and Trademark Office	-	

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on

2 June 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackool (US 5,354,265).

Mackool teaches a continuous sleeve 18 as claimed, wherein the sleeve can be made out of rigid plastic or "other suitable material" (col. 5, lines 26-28).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mackool (US 5,354,265) in view of Hood et al (US 5,746,713).

Mackool teaches all the claimed subject matter except for the sleeve being made out of metal. Hood teaches a similar sleeve wherein it can be made out of either rigid plastic or metal (col. 3, lines 44-45). In view of Mackool's teaching that "other suitable material" can be used for the sleeve, it would have been obvious to one of ordinary skill in the art to use metal as taught by Hood to make the device of Mackool, particularly since Hood teaches the interchangeability of metal with rigid plastic.

Response to Arguments

Applicant has argued that the Examiner has improperly treated the entire preamble of claim 12 as functional. Applicant has cited several legal authorities that the preamble must be considered. The Examiner agrees completely that the preamble must be considered. And, as stated in the previous office action, the Examiner has, in fact, considered the preamble in its entirety. The Examiner also agrees that functional recitations must be given appropriate patentable weight, i.e. to the extent that they limit the structure of the accompanying positively recited limitations.

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In the previous office action, the Examiner gave an example of how a functional recitation can limit the structure of positively recited limitations. (sample claim 1). In the interest of presenting the argument in a different way, the examiner will discuss instant claim 12, with particular regard to the functional limitations of the ultrasonic probe/fragmentation device, and how they limit the structure of the protective sheath.

Let's look at the claim in reverse, since this is really how it must be interpreted in this case. First we have the body of the claim, which sets forth the positively recited limitations of the sheath.

". . . said protective sheath comprising:

a continuous hollow sleeve having a proximal end and a distal end, said sleeve being configured to surround the elongate ultrasonic probe and extend therealong when said sleeve and probe are aligned; . . ."

So far, we have a tube of reasonable length and size to fit around an ultrasonic probe of unspecified size.

"... a connection on the proximal end of the hollow sleeve to connect the hollow sleeve to the housing; ..."

This adds the requirement of a connection on the proximal end that can mate with a housing of a fragmenting device. (See Mackool, figures 7-8, element 30).

"...an inner surface of the hollow sleeve formed, shaped, and sized to prevent contact with the outer surface of the elongate ultrasonic probe along its length so that there is generally a clearance between the inner surface and the outer surface when said sleeve and probe are aligned; ..."

This means that the tube has an inner diameter slightly bigger than a probe of unspecified size.

". . . and said inner surface having an inside diameter adjacent the flange when the sheath is aligned with the probe, that is generally and substantially the same as the outside of the flange thereby forming generally a barrier to the passage of material into the clearance.

This means the tube has an inner diameter at some location that is the same as a flange of unspecified size.

So at this point we still have a tube of reasonable length and diameter, further having a connection for connecting to a housing of a fragmenting device.

Now, on to the functional language of the preamble, and how it limits the structure of the tube.

"12. A protective sheath for use with an elongate ultrasonic probe of an ultrasonic fragmenting device, . . ."

The tube must be of a reasonable size to fit around an ultrasonic probe. This doesn't even restrict the size to that of phacoemulsification probes. Just ultrasonic probes in general.

"... said device having a housing..."

We covered this above.

"... and an ultrasonic horn within and attached to said housing, wherein the elongate ultrasonic probe is configured for attachment to the ultrasonic horn, has an outer surface about and along its length, has vibratory nodes spaced along its length, ..."

This means the connection must be around *something* (i.e. the ultrasonic horn), which does not really restrict the size or shape of the connection. The vibratory nodes are not structural features, but rather locations where the ultrasound waves do not

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vibrate the probe. Since this does not give the probe any different size or shape, the tube does not need any different size or shape to fit around it.

"... and has a flange that circumscribes the elongate ultrasonic probe at or near the most distal vibratory node of the probe, ..."

This is the passage that Applicant seems to think limits the structure of the tube. However, this does not require any specific size or shape tube to fit around it. We don't know how big the flange is. We don't even know how big it is relative to the other probe structure, except that it sticks out radially to some unspecified radius from the outer diameter of the probe. Therefore, this does not place any size or shape restrictions on the tube that is positively claimed.

So coming back to the tube. We still have a tube of reasonable length and diameter, further having a connection for connecting to a housing of a fragmenting device. Just like we did before considering the preamble. This makes sense, because according to Applicant's own figure 2, hollow sleeve 19 is simply a straight tube, with a single diameter, further having a connection for connection to a housing. Mackool teaches this same structure with element 18, i.e. a straight tube, with a connection.

As a clarification, the Examiner would also like to address Applicant's comments regarding the Examiner's sample claim 1 in the previous office action. Applicant remarked that their claim 12 is just like the Examiner's sample claim 1. If, by this comment, Applicant means that the functional material in claim 12 must be considered and given appropriate weight, the Examiner agrees. Accordingly, the Examiner HAS considered the functional material in claim 12, but it simply does not limit the sleeve

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structurally, as does the functional material in sample claim 1. The sleeve can be a straight tube with a connection, and still fit over applicant's functionally claimed ultrasound probe, even with all its nodes, flanges, etc. In fact, Applicant's sleeve IS a straight tube with a connection.

Conclusion

This is a RCE of applicant's earlier Application No. 09/829,678. All claims are drawn to the same invention claimed in the earlier application and were finally rejected on the grounds and art of record. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt (June 9/2003

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700